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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3758]

Agency Information Collection Activities; Proposed Collection; Comment Request; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with expanded access to investigational drugs for treatment use.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-3758 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Expanded Access Applications." Received comments, those filed in a timely manner (see

ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910-0814--Revision

This information collection supports Agency regulations in 21 CFR part 312, subpart I, Expanded Access to Investigational Drugs for Treatment Use; associated guidance; and Form FDA 3926, Individual Patient Expanded Access Investigational New Drug Application (IND).

The regulations govern the use of investigational new drugs, biologics, and approved drugs if availability is limited by a risk evaluation and mitigation strategy, when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The goal of the expanded access program is to facilitate the availability of such products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition. The regulations provide that certain criteria be met, establish content and format requirements for associated reporting, and require that submissions include a cover sheet.

Although we continue to account for burden associated with the submission of expanded access requests for individual patients, we are revising the information collection to also account for burden attendant to other expanded access submissions, including commercial investigational new drug applications (INDs) that involve large groups of patients enrolled for treatment use of the investigational drug (§§ 312.300 through 312.320 (21 CFR 312.300 through 312.320)), currently approved under OMB control number 0910-0014. Because of FDA's long history of facilitating expanded access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions, our efforts in this regard are ongoing.

Form FDA 3926 was developed to assist respondents to the information collection. Form FDA 3926 requires the completion of data fields that enable us to uniformly collect the minimum information necessary from licensed physicians who want to request expanded access as prescribed in the applicable regulations. To supplement the form instructions, we issued guidance, most recently updated in October 2017, entitled "Individual Patient Expanded Access Applications: Form FDA 3926," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/individual-patient-expanded-access-applications-form-fda-3926. As discussed in the guidance, § 312.310(b) contains additional submission requirements for individual patient expanded access requests. These respondents may continue to use either Form FDA 3926 or Form FDA 1571, Investigational New Drug Application (IND),

for all types of IND submissions to satisfy requirements in 21 CFR 312.23(a) (approved under OMB control number 0910-0014). FDA considers a completed Form FDA 3926 signed by the physician and checked in the box in Field 10.a (Request for Authorization to use Form FDA 3926) to be a waiver request in accordance with 21 CFR 312.10.

We are proposing the following revisions to data elements in Form FDA 3926 and will make corresponding revisions to the form instructions:

- Reorder Field 8, "Physician Name, Address, and Contact Information" to Field 1, and renumber remaining data fields accordingly;
- Add "Race and Ethnicity" as an optional item under the "Clinical Information/Brief Clinical History" field;
- Add "Request for Withdrawal" under the "Contents of Submission" field;
- Add technological enhancements to the electronic version of Form FDA 3926 that utilize user-based selections to prompt required data field entries. Currently, certain fields become grayed out if not required for the submission type selected.

Data elements in §§ 312.315 and 312.320 continue to be reported in Forms FDA 1571 and 1572, Statement of Investigator, (approved under OMB control number 0910-0014).

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden--Center for Drug Evaluation and Research[1]

21 CFR part 312, subpart I; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 3926	1,204	2.4958	3,005	0.75 (45 minutes)	2,254
§ 312.310(d); submissions related to emergency use of an investigational new drug: Form FDA 3926	1,265	2.843	3,596	16	57,536
§§ 312.315(c) and 312.305(b); submissions related to expanded access and treatment of an intermediate-size patient population[2]	88	3.64	320	120	38,400
§ 312.320(b); submissions related to a treatment IND or treatment protocol[2]	20	7	140	300	42,000
Total			7,061		140,190

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910-0014.

Table 2.--Estimated Annual Reporting Burden--Center for Biologics Evaluation and Research[1]

21 CFR part 312, subpart I; Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§§ 312.310(b) and 312.305(b); number of submissions related to expanded access and treatment of an individual patient: Form FDA 3926	118	1.305	154	8	1,232
§ 312.310(d); number of submissions related to emergency use of an investigational new drug: Form FDA 3926	1,591	4.2137	6,704	16	107,264
§§ 312.315(c) and 312.305(b); number of submissions related to expanded access and treatment of an intermediate-size patient population[2]	28	1	28	120	3,360
§ 312.320(b); number of submissions related to a treatment IND or treatment protocol[2]	15	1	15	300	4,500
Total			6,901		116,356

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910-0014.

The information collection reflects an increase in 254,750 burden hours and 11,568 responses annually since the last OMB review and approval of the information collection. We attribute this to an increase in the number of submission.

Dated: December 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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